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EXAMINER	
HANDY, DWAYNE K	
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1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/674,457	Applicant(s) Anderson et al.	
	Examiner Dwayne K. Handy	Art Unit 1743	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on ______ .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *20-41* is/are pending in the application.

4a) Of the above, claim(s) ______ is/are withdrawn from consideration.

5) ☐ Claim(s) ______ is/are allowed.

6) ☒ Claim(s) *20-41* is/are rejected.

7) ☒ Claim(s) *29 and 30* is/are objected to.

8) ☐ Claims ______ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on ______ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on ______ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ______ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *7-9, 11*

18) ☐ Interview Summary (PTO-413) Paper No(s). ______

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 29 and 30 are objected to because of the following informalities:

In claims 29 and 30, applicant has referred to "the method of..." in the preamble of the claims. Claims 29 and 30, however, are drawn to a device and not a method. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 20-24, 26, and 29-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (6,143,248). Kellogg teaches a device for performing microanalytic and

microsynthetic analyses and procedures, such as microminiaturization of genetic, biochemical and chemical processes related to analysis, synthesis and purification of biological, chemical, environmental and other compounds. The device includes capillary microvalves for controlling fluid flow from reservoirs into transfer channels. The embodiment most relevant to the instant application is shown in Figures 1A-3B and 11A-13. The basic embodiment and description of using the device is disclosed in column 6

(63) In a second embodiment of the invention is provided a centrifugal rotor or Microsystems platform for providing centripetally-motivated fluid micromanipulation, wherein a volume of a fluid sample, most preferably comprising a biological sample, in a fluid chamber of the rotor or platform is approximately completely displaced in the chamber by replacement of the volumetric capacity of the chamber with an amount of a displacement fluid. In such embodiments of the invention, said rotor or platform is a rotatable platform, comprising a substrate having a first flat, planar surface and a second flat, planar surface opposite thereto, each surface comprising a center about which the platform is rotated. In said centrifugal rotor or microplatform is provided a first surface that comprises the following components in combination:

(64) 1. An entry port comprising a depression in the first surface having a volumetric capacity of about 1 to about 150 .mu.L and that is accessible to an operator for application of a fluid sample, most preferably a fluid comprising a biological sample. The entry port is fluidly connected with

(65) 2. A first microchannel which defines a cross-sectional area of about 0.02 mm to about 1 mm in diameter that extends radially from the center of the platform and defines a first end proximally arrayed towards the center of the platform and is fluidly connected with the entry port, and a second end distally arrayed from the center of the platform. A capillary junction is formed between the proximal end of the microchannel and the entry port that prevents further fluid flow in the absence of the application of centripetal force applied by rotating the rotor or platform. Fluid placed into contact with the first end of the capillary at the entry port does not flow into the microchannel unless centripetal force is applied to the fluid by rotating the rotor or platform.

(66) The first microchannel is further fluidly connected with

(67) 3. A first fluid chamber having a depth in the surface of the platform equal to or greater than the first microchannel and positioned radially more distant from the center of the platform than the entry port. The entry port, microchannel and first fluid chamber are arrayed on the surface of the platform so that rotation of the platform at a first rotational speed motivates displacement of the fluid in the entry port through the first microchannel and into the first fluid chamber.

(68) The rotor or platform further comprises

(69) 4. A second fluid chamber containing a volume of a displacement fluid, that is fluidly connected with

(70) 5. A second microchannel, wherein the second microchannel extends radially from the center of the platform and defines a first end proximally arrayed towards the center of the platform and a second end distally arrayed from the center of the platform. The second microchannel is fluidly connected with the second fluid chamber at the first end of the microchannel and the second microchannel is fluidly connected with the first fluid chamber at the second end of the microchannel. Rotation of the platform at the first rotation speed does not motivate flow of the displacement fluid through the second microchannel. The second microchannel comprises a material that is not "wettable" by the displacement fluid, so that fluid placed into contact with the first end of the capillary at the second fluid chamber does not flow into the microchannel unless centripetal force is applied to the fluid by rotating the rotor or platform at a higher rotational speed than the first rotational speed. Alternatively, the difference in cross-sectional area of the microchannel and the second fluid chamber is sufficient to form a capillary junction at the first end of the microchannel, so that fluid does not flow into the microchannel unless centripetal force is applied to the fluid by rotating the rotor or platform at a higher rotational speed than the first rotational speed.

(71) The platform further comprises

(72) 6. A third fluid chamber comprising a displacement fluid that is fluidly connected with

(73) 7. A third microchannel, wherein the third microchannel extends radially from the center of the platform and defines a first end proximally arrayed towards the center of the platform and a second end distally arrayed from the center of the platform, wherein the third microchannel is fluidly connected with the third fluid chamber at the first end of the microchannel and wherein the third microchannel is fluidly connected with the first fluid chamber at the second end of the microchannel. Rotation of the platform at the first rotation speed does not motivate flow of the fluid sample through the third microchannel.

(74) Rotation of the platform at the second rotational speed motivates flow of the displacement fluid from the second fluid chamber, through the second microchannel and into the first fluid chamber, wherein flow of the displacement fluid into the first fluid chamber forces the fluid in the first fluid chamber through the third microchannel and into the third fluid chamber. In preferred embodiments, displacement fluid flow into the first fluid chamber is laminar and without turbulence, that is, the displacement fluid forces the fluid, most preferably a biological sample fluid, out of the first fluid chamber and into the third microchannel without mixing of the sample fluid and the displacement fluid.

(75) In a preferred embodiment, the rotatable platform has a diameter of about 20 mm to about 400 mm. In a preferred embodiment, the entry port is from about 0.25 mm to about 1 mm deep. In a preferred embodiment, the entry port is positioned from about 1 cm to about 20 cm. In a preferred embodiment, each of the fluid chambers is from about 0.25 mm to about 1 mm deep. In a preferred embodiment, each of the fluid chambers comprises a volume of about 1 .mu.L to about 150 .mu.L. In a preferred embodiment, each of the fluid chambers radially extends from about 15 mm to about 115 mm from the center of the platform. In a preferred embodiment, the first rotational speed is from about 10 rpm to about 500 rpm. In a preferred

embodiment, the second rotational speed is from about 100 rpm to about 2000 rpm. In a preferred embodiment, a volume of from about 1 .mu.L to about 150 .mu.L is displaced from the first fluid chamber into the third fluid chamber by laminar displacement fluid flow from the second fluid chamber to the first fluid chamber at the second rotational speed.

(76) In the practice of the invention is also provided a method for moving a fluid in a microsystem platform of the invention. In this embodiment, the invention provides a method having the steps of

(77) 1. Applying an amount of a fluid sample, most preferably a biological fluid sample to the entry port of the rotatable microsystem platform, the sample comprising a volume of about 1 to about 1 .mu.L. In preferred embodiments, the biological fluid sample is a blood drop.

(78) 2. Rotating the platform at a first rotation speed for a time sufficient to displace the fluid in the entry port into the first fluid chamber.

(79) 3. Rotating the platform at a second rotation speed that is greater than the first rotational speed to displace the displacement fluid through the second microchannel and into the first chamber. The displacement fluid is introduced into the first chamber by laminar flow, wherein the displacement fluid does not mix with the fluid, most preferably a fluid comprising a biological sample, in the first fluid chamber. Movement of the displacement fluid by laminar flow into the first fluid chamber forces the fluid in the first fluid chamber, most preferably a fluid comprising a biological sample, through the third microchannel and into the third fluid chamber.

As to the use of capillary valves based on surface tension, Kellogg shows the use of capillary valves which involves hydrophobic and hydrophilic surfaces (defined by contact angle) wetting angle) in Figures 2A-3B and disusses them further in column 15-21. In Figure 9, Kellogg shows a scheme for flowing material from a reservoir through a channel and to a next reservoir. In column 29, Kellogg states how material is kept in the reservoir by a change in contact angle at the interface of reservoir and channel.

(110) 2. Centrifugal rotors, microplatfonms and Microsystems arc also fabricated comprising material having contact angles <90.degree. and other material having contact angles >90.degree.. For example, using aqueous solutions a fluid reservoir may be hydrophilic (contact angle <90.degree.), whereas a tube or channel is fabricated from a material having a contact angle >90.degree. (thereby requiring positive pressure to be applied to motivate fluid flow from the reservoir into the channel).

Kellogg shows multiple channels and inlet ports in Figures 11A-12. Finally, the Examiner believes that passing both water and/or cellular material through the channels would meet the surface tension limitations of the instant claims.

Inventorship

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248). Kellogg, as described above in paragraph 3, teaches every element of claim 25 except for a channel outlet. It would have been obvious to one of ordinary skill in the art to provide an outlet. One would provide a channel outlet toward the end of the channel to remove materials from the channel so that either the channel may be filled again, or to further process the contents of the channel.

8. Claims 27-28 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kellogg et al. (6,143,248) in view of Sheppard, Jr. et al. (6,143,247). Kellogg, as described above in paragraph 3, teaches every element of claimd 27-28 except for treating the channels to

enable cell culture and treating the subtrate with plasma treatment. Sheppard also teaches a circular device for detecting and quantifying particulate matter suspended in a fluid. The invention provides an integrated, affinity-binding based, analytical system comprising a platform for performing an affinity-binding based assay for specifically binding particulates including microbial cells, and a detection means for detecting the particulates specifically bound to a defined surface or chamber comprising the platform. Methods for using the analytical systems of the invention are also provided. Sheppard specifically mentions cell capturing and testing in column 4, lines 31-60. Sheppard also teaches surface modification through plasma deposition (column 16, lines 9-37) - including the use of materials which will attact and bind cellular material. It would have been obvious to one of ordinary skill in the art to combine the plasma coating of the cell affinity material of Sheppard with the device and methods of Kellogg. One would add the cellular material to perform capture and analysis of cellular material as taught by Sheppard. One would use the plasma coating method since it is a well known substrate coating method which can be used to coat the cellular affinity materials of Sheppard onto a substrate.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nelson et al. (6,074,827), Sheppard, Jr. et al. (6,319,468), and Mian et al. (6,319,469) teach circular microfluidic devices which use centrifugal force to drive fluids through the chambers of the device. Cathey et al. (5,798,215), Fare et al. (5,992,820), and Buechler

(6,271,040) teach microfluidics which control fluid movement through the application of hydrophobic and hydrophilic areas on the substrate.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

June 29, 2003